

REMARKS / ARGUMENTS

Claims 74-84 and 94 are under consideration and are presently rejected.
Claims 85-93 are withdrawn.

Rejection under 35 U.S.C. 103


Examiner has rejected claims 74-84 and 94 as being unpatentable over Lipford (Vaccine 1994 12(1) 73-80) in view of the teachings of Kensil (US 5583112). The Examiner explains that Lipford teaches the making of an immunogenic composition comprising 5mg of cholesterol and 0.4mg of Quil A and that the ratio of cholesterol to Quil A is 12.5:1. The Examiner correctly points out that Lipford does not teach the use of purified QS21. The Examiner also discusses Kensil, which teaches QS-21, a component of Quil-A, has immunogenic properties. The Examiner concludes, therefore, that it would be obvious to a person of ordinary skill in the art to substitute QS21, one of the purified saponins of Kensil, for the crude Quil A extract used in Lipford, and thereby arrive at the Applicants' claimed invention.

With respect, Applicants traverse the rejection. For the reasons expressed in Applicants' earlier responses, Applicants maintain that a person of ordinary skill in the art would not combine the teachings of Lipford with the disclosure in Kensil, and therefore would find no motivation to substitute QS21 for the Quil A in the formulations of Lipford. However, assuming for the sake of argument that such a substitution was made, Applicants believe that the claimed invention is still not disclosed or suggested by Lipford or Kensil. Applicants' claims are directed to a composition with a specific ratio of saponin to sterol. Neither Kensil nor Lipford discusses or appreciates the saponin:sterol ratio as disclosed and claimed by Applicants. The Examiner is requested to note that, as taught by Kensil, QS21 forms only 3.7% of Quil A (see Table 1 of Kensil, col 13). Hence if one were to replace the Quil A of Lipford with QS21, thereby eliminating other components (which from Examiner's viewpoint contribute to toxicity) then one would replace the 0.4mg of Quil A with 3.7% x 0.4mg of QS21. The

formulation so-formed would contain 5mg of cholesterol and 0.0148mg QS21. However such a formulation contains a ratio of saponin:sterol of 1:337 which is outside of the presently amended claims. The combined references do not therefore teach or suggest the invention as claimed.

In light of the above argument, Applicants request that the Examiner withdraw the rejection and favourably reconsider the claims as presented.

Respectfully submitted,



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